UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

RONALD MONK, Individually and on Behalf of All Others Similarly Situated,	:	
Plaintiff,	:	Civil Action No. 10-4841 (FLW) (DEA)
vs.	:	
JOHNSON & JOHNSON, WILLIAM C. WELDON, DOMINIC J. CARUSO, COLLEEN A. GOGGINS and PETER LUTHER,	:	
Defendants.	:	

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED COMPLAINT

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In accordance with Federal Rule of Civil Procedure 12(b)(6), defendants Johnson & Johnson ("J&J"), Dominic J. Caruso, and Colleen A. Goggins (collectively, "Defendants"), by their undersigned counsel, respectfully submit this memorandum of law in support of their motion to dismiss in part the Second Amended Complaint for failure to state a claim upon which relief can be granted.

Preliminary Statement

From the outset of this lawsuit, Plaintiff has sought to transform the regulatory difficulties of J&J's subsidiary McNeil-PPC, Inc. ("McNeil") into an action for securities fraud. Plaintiff's theory appears to be that if there is enough bad news, someone must have been trying to hide that news from investors.

To this end, the First Amended Complaint was a scattershot set of claims that seemed to include every statement made by four high-level J&J and McNeil executives. This Court's December 19, 2011 opinion on Defendants' motion to dismiss narrowed the case dramatically. It dismissed two of the defendants entirely and limited the allegations against the other two defendants, Dominic J. Caruso and Colleen A. Goggins, to three alleged misrepresentations.

By its Second Amended Complaint, Plaintiff now alleges two additional misrepresentations against Mr. Caruso. In both, Plaintiff mischaracterizes the actual statements that were made (which are reflected in conference call transcripts), taking the statements out of context and thereby changing what was

conveyed on the calls. And in both, Plaintiff employs hindsight to attempt to transform an ordinary internal corporate discussion in emails into something more sinister. Neither representation is actionable.

Among other failings, Plaintiff's allegation that, in an April 20, 2010 conference call, Mr. Caruso misrepresented shipping levels not only misstates the conversation but also fails to allege any loss causation resulting from the misrepresentation – that is, Plaintiff does not allege that J&J's stock fell after the public disclosure of all the allegedly omitted information. Plaintiff's second new alleged misrepresentation is Mr. Caruso's response on a May 11, 2010 conference call to an analyst's "ballpark" estimate of the financial impact of a product recall. This statement is not actionable because, among other reasons, it falls under the safe-harbor provision of PSLRA for forward-looking statements: The response was an estimate of future performance and Mr. Caruso explicitly used cautionary language when discussing what was a rapidly changing situation.

The remainder of the Second Amended Complaint fares no better: Two out of three of Plaintiff's original alleged misrepresentations are deeply flawed, for reasons that were not considered or decided on Defendants' prior motion to dismiss – and therefore not barred by law of the case. Specifically, virtually all of the information allegedly omitted from Mr. Caruso's May 11, 2010 statement about quality control at Fort Washington was *already publicly disclosed*. The

same is true about Plaintiff's only allegation against Ms. Goggins: Plaintiff asserts that in congressional testimony she falsely denied knowledge of an alleged "phantom" retrieval of Motrin, but at the time of Ms. Goggins' statement, Representative Towns already had *publicly disclosed* the product retrieval. No reasonable investor could have been misled when the information that was supposedly omitted was simultaneously disclosed at the same public hearing.

Taken as a whole, Plaintiff's Second Amended Complaint is an opportunistic attempt to transform regulatory and quality control issues faced by J&J's McNeil subsidiary into actionable securities fraud. But Plaintiff's legal theories do not fit the facts: The actions of J&J executives that Plaintiff challenges in hindsight show good faith efforts by executives to address a rapidly-changing situation rather than a scheme to defraud investors.

The new allegations against Mr. Caruso and the allegations against Ms. Goggins should be dismissed in their entirety. In addition, the allegations against Mr. Caruso remaining from the First Amended Complaint should be further limited to those concerning the alleged "phantom" Motrin Retrieval.

Plaintiff's Allegations

J&J is a Fortune 500 company that manufactures and sells pharmaceutical products, medical devices and consumer packaged goods through many subsidiaries. *See* Second Am. Compl. ¶22, Sept. 7, 2012, ECF 83 ("SAC").

McNeil-PPC, Inc. ("McNeil") is one of approximately 250 wholly-owned subsidiaries of J&J. McNeil does not have any publicly issued stock of its own.

Plaintiff's First Amended Complaint, filed on March 11, 2011, alleged that William Weldon (J&J's Chairman and former CEO), Peter Luther (former President of McNeil), Colleen A. Goggins (the former Worldwide Chairman of J&J's Consumer Division) and Dominic J. Caruso (J&J's Chief Financial Officer and Vice President of Finance) made numerous misstatements about McNeil's operations, in violation of Section 10(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder. On December 19, 2011, the Court granted Defendants' motion to dismiss in part. Opinion, Dec. 19, 2011, ECF 33 ("Op."). The Court dismissed the claims against Messrs. Weldon and Luther and narrowed the claims against Ms. Goggins and Mr. Caruso from dozens of alleged misrepresentations to only three, two by Mr. Caruso and one by Ms. Goggins. *Id.* at 2, 47, 51-53. The alleged misrepresentations that survived were:

1. a statement by Ms. Goggins on May 27, 2010, about whether a third-party contractor hired by McNeil purchased certain Motrin products from retail stores, *id.* at 47;
2. a statement by Mr. Caruso on May 11, 2010, about alleged quality control deficiencies at McNeil facilities, *id.* at 51; and
3. a statement by Mr. Caruso on April 20, 2010, about McNeil's recalls of over-the-counter ("OTC") drugs, which did not

specifically mention the purchase of certain Motrin products from retail stores. *Id.* at 53.

Plaintiff's Second Amended Complaint, filed on September 7, 2012, alleges that Mr. Caruso made two additional misrepresentations, for a total of five altogether:

4. in an April 20, 2010 conference call with investors, a statement about J&J's ability to resume normal production and shipping levels, *see* SAC ¶¶184-85; and

5. in a subsequent conference call held on May 11, 2010, a statement about the financial impact of a recent product recall. *See id.* ¶¶201-03.

The Motrin Retrieval or So-Called "Phantom Recall"

On November 20, 2008, during a routine stability testing at McNeil's manufacturing plant in Las Piedras, Puerto Rico, the plant's employees discovered that a batch of Motrin tablets did not dissolve at the specified rate. *See* SAC ¶60. Because McNeil had discontinued production of the Motrin at issue, which had been distributed in 8-count vials, McNeil hired an outside third-party contractor, Inmar, to sample 250 stores to determine whether the Motrin 8-count vials were still available for sale. *See id.* ¶¶60-61.

After the store sampling returned evidence that some of the 8-count vials were still on the shelves, Inmar's third-party subcontractor, WIS International, visited stores believed to sell Motrin 8-count vials and bought back all Motrin 8-count vials that it found (the "Motrin Retrieval"). *See id.* ¶¶ 61, 66.

During 2009, McNeil was in contact with and informed the FDA about the Motrin retrieval, but did not announce a recall of the products. *See id.* ¶¶67-68.

The Recall of Products from the Las Piedras Plant and the FDA Warning Letter

On November 6, 2009, McNeil issued a press release announcing the voluntary recall of a limited number of product lots of Tylenol Arthritis Pain Caplets "after identifying an uncharacteristic smell or taste associated with these lots." *Id.* ¶163. Soon afterwards, on December 18, 2009, McNeil issued a press release expanding the recall of the Tylenol Arthritis Pain Caplets to include all available product lots and explaining that the smell was caused by the presence of the chemical 2,4,6-tribromoanisole ("TBA"). *Id.* ¶164.

On January 8, 2010, the FDA issued McNeil a Form 483 detailing its inspection of the Las Piedras plant in Puerto Rico. *Id.* ¶167. The Form 483 included 17 event investigations and 4 manufacturing "clearance incidences" that the FDA attributed to "cleaning deviations." *Id.* A week later, on January 15, 2010, the FDA sent a "warning letter" addressed to Mr. Weldon and Mr. Luther criticizing McNeil and J&J's quality control procedures and its handling of the investigation into odor complaints ultimately determined to be attributable to the presence of TBA. *Id.* ¶168. For example, the letter stated that "the timing and depth" of the "investigative efforts regarding uncharacteristic odor complaints

were insufficient to meet good manufacturing practice" and that the "Quality Control Unit was not proactive in response to consumer complaints." *Id.*

These events were hardly kept secret: Both the warning letter and the Form 483 were promptly disseminated to the public. The FDA posted both the Form 483 and warning letter on its public website. Phillips Decl.[1] ¶3

On January 15, 2010, McNeil publicly announced an additional TBA recall, expanding it to numerous other Tylenol products and other brands. *See* SAC ¶73. Following the TBA recall, the FDA convened a meeting on February 19, 2010 with McNeil and J&J employees to discuss McNeil's quality control deficiencies. *See id* ¶80. The FDA disclosed the February meeting during a May 4, 2010 press conference and informed the media that the agency had expressed "serious concerns about McNeil's manufacturing operations" during the meeting. *Id.* ¶194.

The Fort Washington Recalls and Suspension of Production

After McNeil discovered black metallic contaminants in bottles of infants' Tylenol, on April 14, 2010, J&J shutdown the liquid manufacturing lines at its Fort

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[1] "Phillips Decl." refers to the Declaration of C. William Phillips submitted on September 27, 2012 in conjunction with Defendants' Motion to Dismiss the Second Amended Complaint. In deciding a motion to dismiss, a court "may consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993).

Washington, Pennsylvania plant. *See id.* ¶176. Following that, on April 30, 2010, McNeil issued a press release recalling all lots of certain OTC Children and Infants' liquid products manufactured in the United States. *See id.* ¶188. On May 4, 2010, the FDA posted a 483 Inspection Report of the Fort Washington Plant documenting the quality control deficiencies at the plant on its public website and held a press conference. *Id.* ¶¶191-92. The FDA held the press conference because the recall of 50 OTC medications "generated a great deal of interest from consumers and the media." *Id.* ¶192. Also on May 4, 2010, McNeil disclosed in a press release that it had temporarily suspended all production at the Fort Washington plant because of quality concerns. *Id.* ¶195.

Caruso's April 20, 2010 Earnings Conference Call

As these events were unfolding, on April 20, 2010, Mr. Caruso and Louise Mehrotra, J&J's Vice President of Investor Relations, held a conference call with analysts concerning J&J's first quarter 2010 earnings. Phillips Decl. Ex. A (Transcript of April 20, 2010 Conference Call); *see* SAC ¶184. In her opening remarks, Ms. Mehrotra discussed the TBA recall, stating that "[s]ales were impacted by the voluntary recall of certain OTC products announced in January" and that "[t]he pace of restocking is accelerating and we are now approaching normal levels of production and shipment for *impacted products*." Phillips Decl. Ex. A, at 3 (emphasis added).

During the question-and-answer portion of the call, an Analyst asked Mr. Caruso: "And just to follow up on OTC, when do you think we will get back to trend line in that business?" *Id.* at 13; SAC ¶184. Because the analyst was following up on Ms. Mehrotra's opening remarks, Mr. Caruso started his response by referring to Ms. Mehrotra's earlier statement about the January TBA recall: "Well, we are currently, *as Louise pointed out*…we resumed obviously production levels and shipment levels are now approaching, this point in this quarter, approaching the normal levels of shipments." Phillips Decl. Ex. A, at 14 (emphasis added). In the Second Amended Complaint, Plaintiff reversed the order of Mr. Caruso's statements and deleted Mr. Caruso's reference to Ms. Mehrotra's earlier statement. *See* SAC ¶184. In his answer, Mr. Caruso also stated that "this OTC recall has not really impacted either physician recommendations or consumer preferences." *Id.*; Phillips Decl. Ex. A, at 14. Shortly after that, another analyst asked Mr. Caruso about whether for the "recall in OTC" he could "quantify the impact in the first quarter and I assume we should see a catch-up in the second quarter, is that correct?" *See* SAC ¶184; Phillips Decl. Ex. A, at 15. Mr. Caruso stated that the OTC business was down in the first quarter and went on to explain:

> As I mentioned earlier…we are now resuming production levels and shipments are now resuming to more normal levels. So I think there will be some improvement obviously in the second quarter, but we still will see some impact from not being on the market in the early part of the second quarter. So we will have to wait and see how that plays out during the second quarter.

See SAC ¶184; Phillips Decl. Ex. A, at 15. Plaintiffs do not allege that this statement, or the information about shipping levels or Fort Washington that was allegedly omitted, had any effect upon the price of J&J's common stock.

Caruso's May 11, 2010 Investor Call

On May 11, 2010, Mr. Caruso and Ms. Mehrotra participated in a conference call with analyst Bob Hopkins of Bank of America Merrill Lynch. SAC ¶¶199, 201; Phillips Decl. Ex. B (Transcript of May 11, 2010 Conference Call). At the beginning of his opening remarks, Mr. Caruso stated: "There may be some forward-looking statements in my prepared remarks or the presentation and those are subject to risks and uncertainties. And of course, they are all available – in terms of disclosure around those risks and uncertainties are available in our publicly filed documents." Phillips Decl. Ex. B, at 2.

In the question-and-answer portion of the call, Mr. Hopkins asked Mr. Caruso a series of questions specifically focused on the recent Fort Washington recall of certain U.S. OTC Children and Infants' liquid products, which had been

announced eleven days earlier, on April 30. Their exchange started with Mr. Hopkins commenting that

> [P]eople seem to be congregating around a number of $200 million to $300 million as impact. And I know you guys don't like to give specific product revenues, but I am just curious if you could comment as to whether or not the public comments are in the right ballpark in terms of revenue impact.

Caruso responded:

> [W]e don't disclose products at all levels in the Company, and these products are below the level that we typically disclose, so I'm not going to disclose the level. But as I said, *it does impact the liquid children's and infant's formulations of the US over-the-counter products*. And if you refer to published sources, the estimate that you provided earlier is not unreasonable. *Id.* at 4; SAC ¶201 (emphasis added)

Mr. Caruso later made additional comments warning that it was difficult to predict the financial impact of the Fort Washington recall and suspension of production. In response to a question about whether the impact of the recall would be called out as a charge or just disclosed, Mr. Caruso said "[a]t the moment, we are still evaluating the situation and refining our estimates, so it is premature for me to comment on the level that this might entail." Phillips Decl. Ex. B, at 2, 4-5. When asked whether "you've identified root causes of the problem that would allow you to remediate this in a reasonable timeframe," Mr. Caruso responded the it would be "premature to tell you now when" production at Fort Washington would resume

"[a]nd in fact, the ultimate resumption of production and shipment is really not known at this time, and it is dependent upon a number of factors." *Id.* at 5.

Mr. Hopkins later asked Mr. Caruso: "In terms of providing a level of confidence that this is a McNeil-specific issue, what could you say to that in terms of giving people comfort that in the larger pharmaceutical business, you are comfortable with your quality systems?" *Id.*; SAC ¶201. Mr. Caruso responded:

> One thing to keep in mind is this is a very specific inspection of one manufacturing plant in our consumer business. The comments by the FDA are very specific to that particular facility…. And this particular instance and this particular recall is reflective of the conditions at the McNeil Fort Washington facility.

SAC ¶201; Phillips Decl. Ex. B, at 5. Mr. Caruso did not address the already publicly disclosed information about J&J recalls, the warning letter from the FDA, the Form 483 for Las Piedras, or the other quality issues that had been the subject of public discussion in the preceding weeks and months.

The May 27, 2010 Congressional Hearing

In light of the public disclosures and recalls, a public congressional hearing was held on May 27, 2010 concerning McNeil's quality control issues. Colleen Goggins testified at that hearing. SAC ¶217; Phillips Decl. Ex. C (May 27, 2010 Hearing of the House Oversight and Government Reform Committee).

At the beginning of the hearing, the Chairman of the Committee, Representative Edolphus Towns, revealed that "[a]ccording to an FDA document, McNeil knew there was a potential problem with one of its Motrin products that was on the market in 2008, but rather than issue a recall, McNeil allegedly sent contractors out to the stores to buy the products back and told the stores not to mention a recall." SAC ¶214; Phillips Decl. Ex. C, at 2. Joshua Sharfstein, Principal Deputy Commissioner of the FDA – the first person to testify at the hearing – also discussed the Motrin Retrieval. Phillips Decl. Ex. C, at 7. Later, Representative Towns questioned Ms. Goggins about her knowledge of the Motrin Retrieval. Representative Towns asked Ms. Goggins: "Did you have contractors go back to stores and buy medicine instead of recalling the medicine?" and she replied "No, we didn't." SAC ¶217; Phillips Decl. Ex. C, at 29. Representative Towns also asked Ms. Goggins whether she knew anything about the contractors being instructed to go into the stores and say "do not mention the fact that this is a recall," and Ms. Goggins responded: "I know nothing about that, sir. I know only that we were in discussions with FDA in San Juan over the product issue and how we were planning to handle it with a third-party – third-party contractor." SAC ¶217; Phillips Decl. Ex. C, at 29. Representative Towns expressed surprise at Ms. Goggins' statement that McNeil was working with the FDA because "the FDA is saying that they learned of this later on." Phillips Decl. Ex. C, at 29.

Later in his questioning Representative Towns said:

> [t]his document that was actually just brought to my attention says this: "You should simply act like a regular customer while making these purchases. There must be no mention of this being a recall of the product. If asked, simply state that you employer's checking the distribution chain of this product and needs to have some of it purchased for the project. It's a demonstration project, and we want to purchase it for the demonstration project." Is this accurate?

Ms. Goggins responded: "As I said sir, I have no idea." *Id.* at 37. Finally, during his closing remarks Representative Towns again stated: "[W]e uncovered a J&J document showing that they told their contractors not to say this is a recall, just buy up everything." *Id.* at 40.

The Court Dismisses Most of Plaintiff's Alleged Misrepresentations

The initial complaint in this action was served in September 2010. Plaintiff served an Amended Complaint on March 11, 2011.

On December 19, 2011, Judge Wolfson granted Defendants' motion to dismiss in part, holding that dozens of alleged misrepresentations that Plaintiff had included in the Amended Complaint were not actionable. The Court dismissed two defendants (Messrs. Weldon and Luther) altogether, and narrowed the claims against Mr. Caruso and Ms. Goggins to three alleged misstatements, two made by Mr. Caruso and one made by Ms. Goggins.

The Court found that it was plausible that Mr. Caruso's statement on the April 20, 2010 earnings call that the "OTC recall has not really impacted either physician recommendations or consumer preferences" could be found to be misleading to investors because it did not mention the Motrin Retrieval and that plaintiff had adequately pleaded scienter with respect to that statement. Op. at 53-54. The Court also held that a strong inference of scienter could be drawn from Mr. Caruso's statement on the "May 11, 2010 conference call that… '*The comments by the FDA were specific to that particular facility*…And this particular instance and this particular recall is reflective of the conditions at the McNeil Fort Washington facility.'" *Id.* at 51 (emphasis in original.) The Court found that the statement created "a duty to disclose McNeil's general quality control deficiencies, the phantom recall, the other recalls." *Id.* Lastly, the Court found that plaintiff's allegation that Ms. Goggins testified that she did not know about the Motrin Retrieval or "Phantom recall" at the May 27, 2010 hearing when in fact she did and acted with scienter when doing, so was "plausible." *Id*. at 47.

The New Allegations in the Second Amended Complaint

Plaintiff's Second Amended Complaint alleges two new misrepresentations by Mr. Caruso, one during the April 20, 2010 earnings call and one during the May 11, 2010 conference call.

1. The April 20 Allegation Regarding Shipping Levels. Plaintiff alleges that Mr. Caruso's statements on the April 20, 2010 call that shipments are now "approaching the normal levels" and "are now resuming to more normal levels" were false and misleading because [redacted][2]

[2] It is worth noting that Plaintiff has been aware of these statements, which are publicly available, since his first Complaint was filed. Indeed, he relied upon the same transcript for claims brought in his Second Amended Complaint.

[redacted]

2. The May 11 Allegation Regarding Financial Impact. The second new statement that Plaintiff alleges is Mr. Caruso's comment to Mr. Hopkins on the May 11, 2010 conference call that, "if you refer to published sources, the [$200 to $300 million] estimate that you provided earlier [for the revenue impact for the Fort Washington recall] is not unreasonable." SAC ¶201; Phillips Decl. Ex. B, at 4

[redacted]

[redacted]

Argument

To state a claim for securities fraud under Section 10(b) of the Exchange Act and Rule 10b-5, a plaintiff must allege "(1) a specific false representation [or omission] of material fact; (2) knowledge by the person who made it of its falsity; (3) ignorance of its falsity by the person to whom it was made; (4) the intention that it should be acted upon; and (5) that the plaintiff acted upon it to his damage."

In re Rockefeller Ctr. Props., Inc. Secs. Litig. ("Rockefeller"), 311 F.3d 198, 216 (3d Cir. 2002) (citation omitted). Following the Supreme Court's decision in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007), a plaintiff must show that the facts alleged in the complaint "'raise a right to relief above the speculative level.'" *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly*, 550 U.S. at 555); *see id.* ("[W]e decline at this point to read *Twombly* so narrowly as to limit its holding on plausibility to the antitrust context.").

Plaintiffs seeking to bring securities fraud claims have an even higher pleading burden: Securities fraud claims must comply not only with the particularity requirements of Fed. R. Civ. P. 9(b), *In re Suprema Specialties, Inc. Secs. Litig.*, 438 F.3d 256, 276-77 (3d Cir. 2006), but also must meet the "[e]xacting pleading requirements" of the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007). Congress intended the PSLRA to act "[a]s a check against abusive litigation by private parties," *id.*, by, among other things, "substantially heighten[ing] the existing pleading requirements." *Rockefeller*, 311 F.3d at 217 (internal citation and quotations omitted).

Plaintiff's new allegations of two misrepresentations by Mr. Caruso distort what Mr. Caruso actually said. Neither statement was misleading because of the information conveyed in the conversation as well as the information already in the

public sphere. For the alleged misstatement regarding shipping levels, Plaintiff does not even claim that it was the cause of any loss. And Mr. Caruso's statement regarding the financial impact of one of the recalls is protected by the PSLRA's safe harbor for forward-looking statements.

In addition, two of Plaintiff's previously alleged misrepresentations, which survived Defendants' previous motion to dismiss, are not actionable for reasons not considered before. Ms. Goggins' congressional testimony could not have misled anyone about the Motrin Retrieval when the Retrieval was publicly disclosed in detail in the same hearing. Mr. Caruso's alleged omission of quality issues could not have misled in light of the many public disclosures of recalls and quality problems at McNeil. These claims also should be dismissed.

Point I.

MR. CARUSO'S STATEMENTS ABOUT SHIPPING LEVELS ARE NOT ACTIONABLE.

The Second Amended Complaint challenges for the first time Mr. Caruso's statements on the April 20, 2010 call that shipments are now "approaching the normal levels" and "are now resuming to more normal levels," as false and misleading, [redacted] These allegations do not state a securities fraud claim because (1) Mr. Caruso's statements accurately addressed only products impacted by the TBA

recall from the Las Piedras facility, not all products – which is clear from what was said on the call; (2) Plaintiff does not adequately allege the necessary state of mind to establish that Mr. Caruso had scienter; and (3) Plaintiff does not allege any loss causation – the allegations do not causally connect Mr. Caruso's alleged omission to any decrease in the price of J&J stock.

A. Mr. Caruso's Statement About Shipping Levels Was Accurate.

Plaintiff's claim that Mr. Caruso's misrepresented shipping levels rests upon a distortion of what Mr. Caruso said: Plaintiff accuses Mr. Caruso of misleading investors by "falsely assur[ing] the market that J&J's OTC business was returning to 'normal'" and "reporting to investors that the Company was currently 'approaching the normal level of shipments.'" SAC ¶ 9; *see also* ¶ 184 ("Caruso falsely assured the market that J&J's OTC business was stabilizing in the wake of the earlier limited recall and that consumer preferences had not been impacted.") What Plaintiff leaves out, when plucking out of the transcript, is the context of the statement, which shows that the remarks did not apply to products generally but were specifically limited to the products affected by the recall.

Before Mr. Caruso spoke on the call, his colleague Ms. Mehrotra introduced his remarks by disclosing that:

> Sales were impacted by the voluntary recall of certain OTC products announced in January, compounded by a less severe cold and flu season. Shipments throughout the quarter were lower than normal as the Company took a very comprehensive approach to the investigation, remediation and resumption of production to ensure these products met quality standards. The pace of restocking is accelerating and we are now approaching normal levels of production and shipment *for the impacted products*.

Phillips Decl., Ex. A, at 3 (emphasis added).

In the Second Amended Complaint, Plaintiff has reversed the order of Mr. Caruso's statements and has deleted Mr. Caruso's reference to Ms. Mehrotra's earlier statement – all in an effort to obscure the fact that Mr. Caruso linked his statements to Ms. Mehrotra's prior statement. *See* SAC ¶184. As the transcript shows, however, when Mr. Caruso commented on shipping levels, he explicitly referred back to Ms. Mehrotra's statement by saying "as Louise pointed out" and used the same language that she used: "[s]hipment levels are now approaching, this point in this quarter, approaching the normal level of shipments." Phillips Decl., Ex. A, at 14. Shortly after, Mr. Caruso made almost exactly the same statement about shipping levels again, and again linked his statement back to his earlier statement by saying, "[a]s I mentioned earlier." *Id.* at 15. Mr. Caruso's remarks concerned the recalled products from McNeil's Las Piedras facility, nothing more.

Plaintiff mischaracterizes this statement as an assurance that sales of OTC products generally, at all facilities, were returning to normal levels, but that is

clearly neither what Mr. Caruso nor Ms. Mehrotra said on the call. The claim for fraud fails, because the allegedly fraudulent statement was, in fact, accurate.[3]

B. Plaintiff Does Not Allege that Mr. Caruso Acted With Requisite Scienter.

Plaintiff must establish a strong inference of scienter to have a viable claim. Scienter is a "mental state embracing intent to deceive, manipulate, or defraud," *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976), and "requires a knowing or reckless state of mind." *Institutional Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009) (internal citation omitted). For scienter, the PSLRA "marks a sharp break with Rule 9(b)," and does not permit a plaintiff to plead scienter generally. *Id.* (citations omitted). The PSLRA's "exacting pleading standard for scienter" requires that a complaint "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* (citing *Tellabs*, 551 U.S. at 313) (internal quotations and brackets omitted).

In *Tellabs*, the Supreme Court concluded that for an inference of scienter to

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3 [redacted] As the transcript of the call shows, Mr. Caruso's statements referred only to the shipping levels of OTC drugs impacted by the January TBA related recall of products from McNeil's Las Piedras facility. *See Backman v. Polaroid Corp.*, 910 F.2d 10, 16 (1st Cir. 1990) (en banc) (holding that "[the duty to disclose rule] does not mean that by revealing one fact about a product, one must reveal all others that, too, would be interesting, market-wise[.]")

be "strong," it must be more than "merely 'reasonable' or 'permissible'" – scienter allegations must be "cogent and compelling." 551 U.S. at 324. "A complaint will survive [a motion to dismiss] only if a reasonable person would deem the inference of scienter cogent and *at least as compelling as* any opposing inference one could draw from the facts alleged." *Id.* (emphasis added). Thus, contrary to the usual 12(b)(6) practice of viewing all plausible allegations in the light most favorable to the plaintiff, in determining whether the requisite "strong inference" of scienter has been established, courts also "must consider plausible nonculpable explanations for the defendant's conduct[.]" *Id.*

[redacted]

C. Plaintiff Does Not Allege Loss Causation.

To plead causation under Rule 10b-5 Plaintiff must allege "(1) 'transaction causation' or ('reliance'), i.e., that but for the fraudulent misrepresentation or omission, the investor would not have purchased or sold the security; and (2) 'loss causation,' i.e., that the fraudulent misrepresentation or omission actually caused the economic loss suffered." *McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 425 (3d Cir. 2007) (internal citation omitted). The Supreme Court's holding in *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336 (2004)

> makes it clear that, 'in order [t]o establish loss causation, a plaintiff must allege . . . that the subject of the fraudulent statement or omission was the cause of the actual loss suffered, i.e., that the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security.'

In re Intelligroup Secs. Litig. ("Intelligroup I"), 527 F. Supp. 2d 262, 297 (D.N.J. 2007) (quoting *In re Winstar Communs.*, Nos. 01 CV 3014(GBD) and 01 CV 11522, 2006 U.S. Dist. LEXIS 7618, at *42 (S.D.N.Y. Feb. 24, 2006)).

As this Court held in *Intelligroup I*, "[i]n other words, the plaintiff is required to plead that the decline in the stock price was caused by the market's discovery of defendant's fraud." *Id.* at 295. "[T]he sole fact that 'a' disclosure [is] made does not establish loss causation." *Id.* at 326. Instead, the plaintiff must allege that "the very misstatement that initially supplied the element of transactional causation, provides the basis for loss causation in the event the stock price falls upon this specific disclosure." *Id.* Thus, in *Intelligroup I*, this Court found that plaintiff did not adequately allege loss causation when it alleged that a series of press releases were interrelated as opposed to directly linking specific disclosures to the decline of the price of the stock. *Id.*

[redacted].

Plaintiff does not allege any drop in the stock from those revelations. The first drop they allege following the disclosure was a decrease of $.91 per share on

May 18, which plaintiff alleges occurred because the FDA announced that it "was expanding its probe of J&J recalls to conduct a 'company-wide investigation' of McNeil's drug manufacturing practices." *Id.* ¶¶207-08 Additionally, to the extent that plaintiff alleges that Mr. Caruso said anything misleading on the April 20 call about the TBA recall, the Second Amended Complaint does not allege any subsequent disclosure that caused the stock to decrease.

In short, Plaintiff makes no allegations of causation whatsoever arising from Mr. Caruso's supposedly fraudulent statements about shipping levels. Without such, the claim for fraud based upon this allegation is not actionable.

Point II.

MR. CARUSO'S STATEMENT ABOUT THE FINANCIAL IMPACT OF THE FORT WASHINGTON PLANT SHUTDOWN IS NOT ACTIONABLE.

The second new alleged misrepresentation is Mr. Caruso's comment to Mr. Hopkins in the May 11, 2010 conference call that "if you refer to published sources, the [$200 to $300 million] estimate you provided earlier [for the revenue impact for the Fort Washington recall] is not unreasonable." *Id.* ¶201; Phillips Decl. Ex. B, at 4 [redacted]

Once again, however, Mr. Caruso's statement is accurate in context. Plaintiff's allegations do not state a securities fraud claim because (1) Mr. Caruso's statement was accurate; (2) Mr. Caruso's statement was a forward-looking

statement accompanied by meaningful cautionary statements; and (3) Plaintiff does not adequately allege scienter.

A. Mr. Caruso's Answer About the Financial Impact on Liquids Was Accurate.

Plaintiff alleges that:

> During the . . . investor conference on May 11, 2010, Defendant Caruso also misrepresented the true revenue impact of the children's OTC recall and Fort Washington plant shutdown when asked a question by an analyst from Bank of America Merrill Lynch:
>
> [Q:] '. . . . [T]here has obviously been a lot of public commentary about the recall. . . . people seem to be congregating around a number of *$200 to $300 million as impact*. . . . I am just curious if you could comment as to whether or not the public comments are in the right ballpark in terms of the revenue impact.'
>
> [A:] 'Well, as you know, we don't disclose products at all levels in the Company, and these products are below the level that we typically disclose, so I'm not going to disclose the level. But as I said, *it does impact the liquid children's and infant's [sic] formulation of the US over-the-counter products*. And if you refer to published sources, *the estimate you provided earlier is not unreasonable*.'

SAC ¶ 201 (emphasis added); Phillips Decl. Ex. B, at 4.

[redacted]

[redacted]

Plaintiff misreads the quotation. As the transcript makes clear, Mr. Caruso referred specifically to the financial impact of the recall of children's liquid OTC products – much of the preliminary language of the call was dedicated to that issue and Mr. Hopkins' precise question began with the comment "I would just like to follow up a little bit, because there has obviously been a lot of public commentary *about the recall*" – the recall of children's liquid OTC products. Phillips Decl. Ex. B, at 4. [redacted]

[redacted]

B. The PSLRA's Safe-Harbor Provision for Forward-Looking Statements Protects Mr. Caruso's Statement About Financial Impact.

The safe-harbor provision of the PSLRA, 15 U.S.C. § 78u-5(c), "applies to statements that are forward looking…provided that they are (1) identified as such and accompanied by meaningful cautionary statements; or (2) immaterial; or (3) made without actual knowledge that the statement was false or misleading." *In re Aetna, Inc. Secs. Litig.*, 617 F.3d 272, 278 (3d Cir. 2010). "The term 'forward-looking statement' is broadly defined to include statements 'containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items'… or statements of 'future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management'" *Avaya*, 564 F.3d at 255 (quoting 15 U.S.C. § 78u-5(i)(1)(A)-(C)).

Mr. Caruso's statement to Mr. Hopkins falls under the safe-harbor provision of the PLSRA. It concerned a projection of revenue and – since it was a response to a long term estimate about the impact of the Fort Washington recall and suspension of production – its accuracy certainly could not be verified at that time the statement was made.

Mr. Caruso also used cautionary language to introduce his statements. He

noted that there would be forward-looking statements in the presentation and referred to J&J's public filings. Phillips Decl. Ex. B, at 2. J&J's then-recently filed 10K stated that forward-looking statements may be identified by words such as "estimates" and their accuracy could be impacted by "[p]roduct efficacy or safety concerns, whether or not based on scientific evidence, resulting in product withdrawals, recalls, regulatory action on the part of the FDA (or international counterparts) or declining sales[.]" *Id.* Ex. F (J&J's 2009 Form-10K, Ex. 99). Furthermore, Mr. Caruso used language that indicated that the statement was forward looking and that investors should consider it with caution: Not only was the statement cautious (he referred Mr. Hopkins to "public sources" and said that the estimate was "not unreasonable") but, in response to a follow up question, Mr. Caruso said that "we are still evaluating the situation and refining our estimates." *Id.* Ex. B, at 4-5. Later he added that "the ultimate resumption of production and shipment [at Fort Washington] is really not known at this time[.]" *Id.*

The decision in *In re Nutrisystem, Inc. Securities Litigation*, 653 F. Supp. 2d 563 (E.D. Pa. 2009), is instructive. In that case, the court found that the statement by the CFO of Nutrisystem on a conference call: "we believe [a competitor's drug's impact] is just a temporary type of thing," was a forward looking statement that fell under the PSLRA safe harbor. *Id.* at 579. Even though the plaintiff alleged that the competitor's drug already was hurting Nutrisystem at the time, the

court held that the statements were not verifiable at the time they were made. *Id.* The CFO's statement was accompanied by sufficient cautionary language because he referenced Nutrisystem's Form 10-K during the call, which included "warnings that a pharmaceutical competitor perceived as easier to use than the Nutrisystem program could negatively impact results and harm the company's competitive position." *Id.* at 579; s*ee also In re Disc. Labs. Secs. Litig.*, No. 06-1820, 2006 U.S. Dist. LEXIS 79823, at *20, *48-53 (E.D. Pa. 2006) (holding that the statement "[w]e anticipate potential approval and commercial launch of Surfax in the United States and potential EMEA approval to occur in the first quarter of 2006" fell under the PLSRA safe harbor even though plaintiff alleged that people at the company knew that the trials did not meet EMEA's clinical standards).

This case is no different. Mr. Caruso's statement was clearly forward-looking. Further, the text abounds with the type of cautionary notes that Congress determined should protect forward-looking statements from liability under the PSLRA. Plaintiff's claims based on these statements should be dismissed.

C. Plaintiff's Allegations Do Not Establish a Strong Inference of Scienter.

The PSLRA's pleading requirement showing a strong inference of scienter necessitates allegations that are more than "merely 'reasonable' or 'permissible'" – scienter allegations must be "cogent and compelling." *Tellabs*, 551 U.S. at 324. "A complaint will survive [a motion to dismiss] only if a reasonable person would

deem the inference of scienter cogent and *at least as compelling as* any opposing inference one could draw from the facts alleged." *Id.* (emphasis added).

Here, Plaintiff offers no compelling reason, but offers merely the benefit of hindsight to argue that Mr. Caruso's statement about Mr. Hopkins' estimate must have been intentionally misleading. Although it turned out later that the Fort Washington shutdown had a $600-million sales impact, that outcome was by no means clear at the time of the May 11, 2010 Conference Call [redacted]

First, as discussed in Point II.A., the transcript of the May 11, 2010 call makes it quite clear that Mr. Caruso was referring specifically to the financial impact of the recall of children's liquid OTC products. Phillips Decl. Ex. B, at 4-5. [redacted] In light of these facts, Plaintiff does not sufficiently allege that Mr. Caruso had an intent to manipulate or deceive when he made the statement.

Point III.

TWO OF PLAINTIFF'S SURVIVING ALLEGED MISREPRESENTATIONS SHOULD BE DISMISSED.

Having chosen to amend his complaint again, Plaintiff's alleged misrepresentations from the prior version of the complaint are subject to a renewed motion to dismiss, on the grounds that they too were not fraudulent given the context of the statements and that Plaintiff failed to plead loss causation.[4]

Specifically, Plaintiff alleges that Ms. Goggins committed securities fraud by denying knowledge of the Motrin Retrieval during a Congressional hearing, but her statement is not actionable because the Retrieval was *publicly disclosed* by Representative Towns at the very hearing where Plaintiff claims Ms. Goggins

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[4] Defendants are not barred by the "law of the case" doctrine from challenging allegations that survived Defendants' previous motion to dismiss. First, the arguments raised here against the surviving allegations – that the alleged misrepresentations were not fraudulent and that Plaintiff has failed to allege loss causation – were not raised or considered in the previous motion. The doctrine only applies to arguments that were actually raised, not ones that could have been raised. *See Quern v. Jordan*, 440 U.S. 332, 347 n.18 (1979); *Cont'l Cas. Co. v. Diversified Indus.*, 884 F. Supp. 937, 949 (E.D. Pa. 1995). Moreover, even if the court finds that law of the case is applicable the "doctrine merely 'directs a court's discretion, it does not limit the tribunal's power.'" *Cont'l Cas.*, 884 F. Supp. at 949 (quoting *Arizona v. California*, 460 U.S. 605, 618 (1983)). Second, Rule 12(g)(2) of the Federal Rules of Civil Procedure does not bar Defendants from moving to dismiss Plaintiffs surviving allegations because it permits the Court to consider the arguments in an effort to avoid unnecessary delay. *In re Westinghouse Secs. Litig.*, No. Civ.A. 91-354, 1998 WL 119554, at *6 (W.D. Pa. 1998) ("There is simply no reason to put the defendant to the time and expense of filing an answer, or both defendant and plaintiff to the time and expense of addressing an issue to be raised later in a motion for judgment on the pleadings, when that issue can easily be resolved now.")

defrauded the public by denying it. Similarly, Mr. Caruso's statement in the May 11 call that "*[t]he comments by the FDA [were] specific to that particular facility [at Fort Washington]*…[a]nd this particular instance and this particular recall is reflective of the conditions at the McNeil Fort Washington facility" were not fraudulent given the context of the public disclosure that already had occurred. SAC ¶199. Both of these alleged misrepresentations should be dismissed.

A. Ms. Goggins' Statement to Congress Denying Knowledge of the Motrin Retrieval Was Not Fraudulent.

Ms. Goggins' statement that she did not know about the "phantom" Motrin recall is not fraudulent because the very information she allegedly concealed – that McNeil hired Inmar to retrieve Motrin 8-count vials from store shelves – had already been publicly announced.[5]

Representative Towns disclosed at the beginning of the hearing that he had FDA "documents" showing that the Motrin Retrieval had taken place. *See* SAC ¶214; Phillips Decl. Ex. C at 2. Joshua Sharfstein, Principal Deputy Commissioner of the FDA, also discussed the Motrin Retrieval during his

[5] Plaintiff alleged in his prior Complaint that Ms. Goggins committed fraud when she denied before Congress that she knew of a supposed "phantom" recall of Motrin the year before. The Court upheld the allegation, reasoning that Plaintiff had sufficiently pled that Ms. Goggins acted with scienter, and that a public statement to Congress could be actionable as a statement to investors. However, the Court did not consider whether the statement could have been considered misleading in light of Representative Towns' statements and documents.

testimony. Phillips Decl. Ex. C, at 7. Representative Towns continuously referenced the "FDA documents" and other evidence of the recalls – at one point projecting one of the documents onto a large screen. *Id.* at 2, 7, 29, 37. In fact, the Motrin Retrieval was described at least three times *before* Ms. Goggins began to testify. *Id*. at 2, 7. The market therefore was aware of the retrieval before Ms. Goggins even began to speak. *In re Burlington Coat Factory Secs. Litig.*, 114 F.3d 1410, 1425 (3d Cir. 1997) (an efficient marker immediately incorporates information into the price of a security).

Representative Towns again referenced the Motrin Retrieval after Ms. Goggins concluded her testimony. Phillips Decl. Ex. C, at 40. At the end of the hearing, Representative Towns asked Ms. Goggins about McNeil's decision not to conduct a formal recall. Ms. Goggins responded: "[A]s I said sir, I have no idea." *Id.* at 37. Ms. Goggins' denial that *she was aware* of the Retrieval is hardly a statement concealing that the Retrieval occurred. Even if it was, the very fact she was supposedly hiding from the public – the existence of the Motrin Retrieval – was disclosed before, during, and immediately after her testimony. In light of the other evidence publicly available at the time, Plaintiff cannot have been materially mislead by nor could he reasonably have relied upon Ms. Goggins' testimony. *See Klein v. Gen. Nutrition Co.*, 186 F.3d 338, 342-43 (3d Cir. 1999) (statements allegedly concealing publicly available information are not material as a matter of

law); *see also In re NAHC, Inc. Secs. Litig.*, No. CIV.A. 00–4020, 2001 WL 1241007, at *16 (E.D. Pa. Oct. 17, 2001) ("Where the information omitted from the allegedly misleading statements was previously or concurrently disclosed, even in another form, this may affect the materiality of the later omission."); *In re Tseng Labs. Secs. Litig.*, 954 F. Supp. 1024, 1029 (E.D. Pa. 1996) ("[T]here can be no liability under the securities laws because of an alleged failure to disclose information that is already available to the public. . . because such information is already part of the total mix.") (internal citation omitted).

B. Plaintiff Does Not Allege that Ms. Goggins' Statement Caused Any Loss.

Plaintiff also does not allege loss causation – that is, that Ms. Goggins' testimony formed the basis for Plaintiff's alleged losses. "In order to set forth a viable 10b-5 claim, the plaintiff must plead that defendant's misrepresentation concealed something from the market that *when disclosed*, negatively affected the value of the security." *In re Intelligroup Secs. Litig. ("Intelligroup II")*, 468 F. Supp. 2d 670, 692 (D.N.J. 2006) (internal citation and quotations omitted).

Plaintiff nowhere explains how Ms. Goggins' statement inflated the stock price given Representative Towns disclosed the Motrin Retrieval before her testimony. And, tellingly, there is no allegation that the stock dropped because of Ms. Goggins' initial denial of knowledge, in the face of Representative Towns' questioning. Plaintiff's claim against Ms. Goggins should be dismissed for this

additional reason. *Intelligroup I*, 527 F. Supp. 2d at 297 (dismissing claims for failure to plead loss causation); *Intelligroup II*, 468 F. Supp. 2d at 692 ("[E]xistence of a causal connection cannot be made solely on the basis of temporal proximity where the stock price decline might be attributable to other forces, events or announcements that took place prior to or contemporaneously with the public airing of the alleged fraud . . .").

C. Mr. Caruso's Statements About the Scope of Quality Issues Were Not Fraudulent.

In the First Amended Complaint, Plaintiff faulted Mr. Caruso for failing to disclose the scope of quality problems when he stated that "the comments by the FDA are very specific to … the conditions at the McNeil Fort Washington facility" during the May 11, 2010 Conference Call. This Court agreed, finding that the statement created "a duty to disclose McNeil's general quality control deficiencies, the phantom recall, the other recalls." Op. 51.

However, other than the Motrin Retrieval, the information that the Court found Mr. Caruso had failed to disclose *was already public*. Plaintiff cannot claim to have been defrauded when the information was public.

- As Plaintiff acknowledges, McNeil issued press releases about the TBA contamination recall from the Las Piedras plant on November 6, 2009, December 18, 2009, and January 15, 2010. *See* SAC ¶¶163-64, 168.
- The January 15, 2010 recall announcement was so significant that analysts were still asking questions about it on the April 20 Conference Call. Phillips Decl. Ex A, at 3, 14-15.

- Additionally, January and February 2010, the FDA posted publicly the warning letter and Las Piedras' Form 483, which not only discussed the TBA recall, but also expressed concern about McNeil's general quality control procedures. *Id*. ¶3

- The FDA disclosed at a May 4, 2010 press conference that the February "extraordinary" meeting between J&J and McNeil at which the agency expressed "serious concerns about McNeil's manufacturing operations" occurred. SAC ¶194.

Because the information that Mr. Caruso allegedly omitted from his statement about conditions at the Fort Washington facility was already public, any omission by Mr. Caruso was not material and no reasonable investor could have relied upon it. *See Klein*, 186 F.3d at 342-43; *NAHC*, 2001 WL 1241007, at *16; *Tseng Labs.*, 954 F. Supp. at 1029.

Conclusion

For the foregoing reasons, Defendants respectfully request that the Court dismiss all of Plaintiff's claims except those based upon Mr. Caruso's alleged omission of the Motrin Retrieval.

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Respectfully submitted,

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